THE SAUNDERS GROUP INC.

K001712

AUG 31 2000

510(k) Summary

Company Name:	**The Saunders Group, Inc.** **4250 Norex Drive** **Chaska, MN 55318-3047**
Telephone:	**952-368-9214**
Fax:	**952-368-9249**
Contact Person:	**Douglas G. Tomasko**
Date Prepared:	**May 31, 2000**
Trade Name:	**3D Activetrac**
Common Name:	**Powered Traction Table**
Classification Name:	**Powered Traction Table (per 21 CFR 890.5900)**

Substantially Equivalent To:

The 3D ActiveTrac Hi-Lo Traction Table is substantially equivalent to products currently in commercial distribution, specifically, the PDS, Inc. DRS System (K981822) and the Henley Tru-Trac 401 Traction (formerly called The Escotek EST Trac Model 401 K844385).

Device Description:

The 3D ActiveTrac is a multi-functional Hi-Lo traction Table. The working surface is 25" wide by 78" long. The Lumbar section is 25" by 45" and will side bend 15 degrees to each side, rotate 15 degrees each direction, and flex 15 degrees up and 15 degrees down. The section is pneumatically powered to extend 6". The foot end of the lumbar section has hooks where the traction belts are to be attached. The thoracic section is 25" wide by 33" long and has a pneumatic powered cervical traction mechanism built into the table. The table has a minimum height of 25" and a maximum height of 37". An electrically powered single-column linear actuator raises and lowers the table. The cervical mechanism and the extending lumbar section of the table are driven by an electronic controlled pneumatic pump. The clinician's input to the electronic controller is through use of the controller's touch screen.

Indications for Use:

The 3D ActiveTrac consists of an adjustable table and a traction force generator. It is designed to exert a therapeutic distraction force on the patient's spine to relieve pressures on structures that may be causing pain. It produces the forces and positions required to cause decompression of the intervertebral discs, that is, unloading due to distraction and positioning. Conditions that may be treated include back pain, neck pain, herniated disc, protruding disc, degenerative disc disease, posterior facet syndrome and sciatica.

Device Testing:

Formal safety and performance testing per UL 2601 or equivalent has not yet been performed on the 3D ActiveTrac. However, required tests including electrical, safety, performance and flammability tests were conducted either on our predicate devices or on the DRS System predicate devices. Further, performance and safety testing of the 3D ActiveTrac will be performed prior to shipment and, the device will be tested and meet the requirements of UL safety standard UL2601 or its equivalent prior to sale.

Biocompatibility Information:

The only materials that will have direct contact with the patient are on the tabletop, traction belts and the cervical neck wedges. These materials have been used in the past and are currently used on marketed devices without any known adverse effects on skin contact. Therefore, biocompatibility testing for these materials is not warranted.

Douglas G. Tomasko
Director of Quality Assurance
The Saunders Group, Inc.
May 31, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Douglas G. Tomasko
Director of Quality Assurance
The Saunders Group, Inc.
4250 Norex Drive
Chaska, Minnesota 55318-3047

Re: K001712
Trade Name: 3D ActiveTrac Hi-Lo Traction Table
Regulatory Class: II
Product Code: ITH
Dated: May 31, 2000
Received: June 5, 2000

Dear Mr. Tomasko:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2: Indications for use Statement

510(k) Number (if Known) K001712

Device Name: 3D ActiveTrac

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(Please Do Not Write Below This Line-Continue On Other Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The- Counter Use _____

(Optional Format 1-2-96)

Donna R. Lochner

vision Sign-Off)
ision of General Restorative Devices
k) Number K001712